

### **REMARKS/ARGUMENTS**

Reconsideration and allowance in view of the foregoing amendment and the following remarks are respectfully requested.

Claims 1, 2, 4-19, 21, 22 and 36 are now pending.

Claim 1 has been amended above to incorporate the limitations of dependent claim 3 and further to specify that the dilation of the incision is carried out with a balloon.

Claims 1, 3-9, 12-14, 16, 21, 22 and 36 were rejected under 35 USC 102(e) as allegedly anticipated by Laufer. Applicant respectfully traverses these rejections.

Claim 1 specifically provides that an incision is formed in the target wall segment and that before a distal end of the flexible conduit is advanced through the wall segment, the incision is dilated with an inflatable balloon. It is respectfully submitted that Laufer does not teach or suggest the use of an inflatable balloon to dilate an incision in the target wall segment before advancement of a flexible conduit therethrough.

More specifically, Laufer teaches a balloon anchor 52,54 in Figure 4 and an inflation member 40 having a perforation element 42 that is apparently inverted before deployment as shown in Figure 1 and everted after perforation of the wall. As clearly disclosed in Laufer, however, only part 44 of inflation member 40 assumes the shape larger than the diameter of the hole and this is for anchoring purposes, after passage through the wall. There is no teaching or suggestion whatsoever of using inflation member 40 to dilate an incision formed in wall 30. Thus, Laufer does not teach or suggest dilating the incision with an inflatable balloon.

Laufer also fails to teach or suggest the features of *inter alia* applicant's dependent claim 19. In this regard, not only does Laufer fail to teach or suggest

dilating an incision with an inflatable balloon, there is no teaching in Laufer providing an inflatable balloon near the distal end of a conduit that retractably receives a needle knife. Indeed, although Laufer teaches a perforating element 42 on inflatable member 40, there is no teaching whatsoever of a retractable needle knife, nor a balloon near the distal end of a conduit that houses a retractable needle knife, as required by applicant's claim 19. It is therefore respectfully submitted that Laufer does not teach or suggest the invention of applicant's claim 1 presented hereinabove nor the limitations of applicant's dependent claim 19. Reconsideration and withdrawal of the rejection over Laufer is solicited.

Claims 1, 2, 4, 5, 7-9, 12, 13, 15-17, 21, 22, and 36 were rejected under 35 USC 102(b) as allegedly clearly anticipated by Wilk. However, as acknowledged by the Examiner, Wilk does not teach or suggest the use of balloons. Thus, the incorporation of dependent claim 3 (to the dilation feature) and further specifically limiting claim 1 to the dilation to being performed with an inflatable balloon clearly distinguishes the invention from Wilk. Reconsideration and withdrawal of the rejection over Wilk is solicited.

Claims 1, 9, 10 and 11-19 were rejected under 35 USC 103 as being unpatentable over Laufer in combination with Wilk and Brosens. Applicant respectfully traverses this rejection.

As noted above, Laufer does not teach or suggest dilating an incision with an inflatable balloon. Moreover, Wilk does not teach or suggest the use of balloons. Brosens teaches a retractor section 32,96 that may be balloon. However, it is expanded solely to prevent the retractor/cannula from being dislodged from the vaginal wall. Brosens does not teach or in any way suggest the use of an inflatable balloon for dilating an incision. Thus, neither Wilk nor Brosens overcome the deficiencies of Laufer with respect to the invention specifically recited in claim 1.

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With regard to applicant's dependent claim 19, it is further noted that although Brosens teaches a balloon that may be expanded to prevent a retractor/cannula from being dislodged from the vaginal wall, Brosens does not teach or suggest the provision of a balloon mounted on the distal end of a needle knife cannula of a needle knife device. Thus, Brosens also fails to overcome the deficiencies of Laufer with respect to applicant's dependent claim 19.

In view of the foregoing, reconsideration and withdraw of the Examiner's rejection based on Laufer, Wilk and Brosens is respectfully requested.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited.

Respectfully submitted,

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